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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,063	02/28/2002	Rocco Casagrande	11641/39	7445

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,063

Applicant(s)

CASAGRANDE ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-200 and 202-214 is/are pending in the application.
- 4a) Of the above claim(s) 1-196 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 197-200 and 202-214 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment of 8/19/05 amended claims 197 and 202-204, and canceled claim 201.

Claims 1-196 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/17/04.

Claims examined on the merits are 197-200 and 202-214.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The disclosure is objected to because of the following informalities: the specification at page 32, line 22, and other places refers to magnetic receptacles 511. However, Figure 5 does not contain "511" as a label designating magnetic receptacles. Additionally at page 33, line 3, reference is made to "substrate 557" and "canted walls 557". How can "557" designate both the substrate and canted walls? The specification should be reviewed for correspondence of the description of the drawings to what is shown by the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 198 and 203-208 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention for reasons set forth in the previous office action of 2/22/05 and for reasons herein.

Claim 198 is unclear how the further experimentation required further limits the device of claim 197. The device of claim 198 is
5 the same as that of claim 197.

Claim 203 and claims dependent thereon are unclear as to the structural relationship of the cell isolation device to the device of claim 197, and structure of the cell isolation device that functions to isolate cells when comprised by the device of claim 197.

10 Claim 208 is unclear how requiring transfer of cells to the isolation device by centrifugal force further limits the isolation device of claim 203 since claim 197 does not require the device to contain cells by being amended in the last line to recite "may be". Claim 208 appears to merely set forth an intended process step without
15 defining additional structure.

Response to Arguments

Applicants urge that further experimentation in claim 197 encompasses any experimentation, and is further narrowed in claim 198 by defining six specific experiments. However, further
20 experimentation in claim 197 is an intended use and does not define structure of the device claimed. Therefore, further limiting the intended use of experimentation does not further limit structure of the device, and claim 198 requires the same device as claim 197.

Applicants urge that claim 203 is clear in view of Figure 5 and
25 the description of pages 7 and 8 of the specification. However, the

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claims and not the figures and description define metes and bounds of the invention. The metes and bounds defined by the claims must be clear without having to rely on the figures and description. Claim 203 provides no structure capable of cell isolation, and it is
5 uncertain as to a device that will be a cell isolation device within the scope of the claim. Furthermore, since claim 203 defines no structure of the isolation device, there is not antecedent basis in claim 203 for structure required in claims 204-208 that depend on claim 203. It is unclear how the structure of claims 204-208 further
10 limits the isolation device of claim 203, and how the structure functions to accomplish cell isolation in connection with the device of claim 197.

Claim Rejections - 35 USC § 103

Claims 197-200, 202-204 and 207-214 are rejected under 35 U.S.C.
15 103(a) as being unpatentable over Ekenberg et al (5,567,326) in view of Dolan et al (6,136,182) and Liberti et al (6,013,532), and if necessary in further view of Zborowski et al (5,968,820) for reasons in the previous office action of 2/22/05 and for reasons herein.

The claims are drawn to a device for arraying cells comprising a
20 substrate having magnetic receptacles and a localized magnetic field gradient such that about one to about five cells associated with magnetic beads may be immobilized in each of the magnetic receptacles.

Ekenberg et al disclose an apparatus for separating magnetically responsive particles. The apparatus contains an array of containers
25 such as a multi well plate, a plurality of magnetically responsive

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pins in a pin plate that form a pin array, and a planar magnet pack above the pin plate. The pins are inserted in the wells, and are caused by the magnet pack to create a magnetic field that separates cells in a medium in the wells due to magnetically responsive particles attached to the cells (col 7, lines 8-27 and col 8, lines 1-40).

Dolan et al disclose a magnetic device for examination and manipulation of cells having magnets configured to provide a vertically-directed gradient so that magnetically-labeled cells are collected on an interior surface of a vessel in an ordered array. For example, see col 6, line 30 to col 7, line 40.

Liberti et al disclose magnetic immobilization and manipulation of cells. A fluid medium is placed in a vessel having a ferromagnetic capture structure including an elongated linear collection surface. The vessel is placed into a magnetic field for inducing a magnetic gradient in a region along the collection surface. Magnetically-labeled cells are attracted toward the collection surface and immobilized thereon in a linear array. For example, see the abstract and cols 5, 6 and 7.

It would have been an obvious to modify the apparatus of Ekenberg et al by replacing the pins with magnets below each well of the multi well plate so that cells labeled with magnetically responsive particles are drawn to and immobilized on the bottom surface of each well as suggested by Dolan et al using magnets configured to provide a vertically-directed gradient so that magnetically-labeled cells are

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collected on an interior surface of a vessel in an ordered array, and
Liberti et al placing a vessel into a magnetic field for inducing a
magnetic gradient in a region along a collection surface where
magnetically-labeled cells are attracted toward the collection surface
5 and immobilized thereon in a linear array. One would have been
motivated to make this modification to provide immobilized cells in a
condition to be observed and further analyzed as in Dolan et al and
Liberti et al. The wells of the apparatus of Ekenberg et al are
inherently capable of immobilizing about one to five cells when only
10 this number of cells is added to each well. The conditions of
dependent claims would have been matters of obvious choice depending
merely on individual preference in view of the disclosures of the
references. The wells of the apparatus of Ekenberg et al can be
considered wells of an isolation device as required by claim 204.
15 Providing micro holes in the bottom and wall of the wells would have
been obvious for fluid flow. The wells will be inherently moved when
the apparatus of Ekenberg et al is moved as in claim 207. The wells
of the apparatus of Ekenberg et al are inherently capable of cells
being transferred by centrifugal force as in claim 208. Zborowski et
20 al further disclose magnetic separation of cells, and if needed, would
have further suggested conditions that can be used.

Response to Arguments

Applicants urge that the references fail to suggest the
limitation of "about one to about five cells" immobilized in each of
25 the magnetic receptacles. However, claim 197 has been amended in the

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last line to recite "may be" before "immobilized in each of said magnetic receptacles". Therefore, the claims do not require the about one to about five cells to be immobilized in each receptacle, but rather require the receptacles to be capable of immobilizing about one to five cells. Furthermore, there is no structure required by the claims to limit the number of cells in each receptacle to only about one to five, and not more than five. The wells of the apparatus of Ekenberg et al are inherently capable of immobilizing about one to about five cells when only this number of cells is about to each well.

10 **Conclusion**

Claims 205 and 206 are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

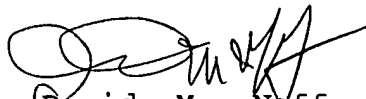
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
15 [direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David M. Naff
Primary Examiner
Art Unit 1651

20 DMN
11/10/05